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SAFETY AND CHALLENGES OF SCAFFOLD USED IN TISSUE ENGINEERING

Tissue Engineering is a rapidly growing area having multidisciplinary science and expertise. This interdisciplinary engineering has attracted much attention as a new therapeutic means that may overcome the drawbacks involved in the current artificial organs and organ transplantation, that have also aiming at replacing lost or severely damaged tissues or organs. The Tissue Engineered Medical Products (TEMP) comprise the biological components such as the cells, tissue, cellular products, biomaterials, biologics or synthetic materials used in combination. Typically the cells are seeded onto a substrate and allowed to proliferate until an adequate amount of tissue or cells are available for transplant to the patient and the 'device' is generally considered as a combination product. *In vitro* and *in vivo* models to evaluate the safety or compatibility of the cellular materials are very specialized and specific. The evaluations include assessment of cytotoxicity, cell adhesion, growth and proliferation, expression of functional phenotype of the cells under consideration etc. However, the combination products need more evaluation on its biocompatibility aspect. The substrate or matrix materials used to 'seed' the cellular materials are subjected to routine materials/device evaluations. Typically these products are considered as implants that may degrade or absorb, leaving only the cellular component behind. Or in other cases, the substrate or protective polymer is considered a permanent implant that allows the cells to function without rejection. The polymer matrix or substrate is subject to biological/safety evaluations. The types and degree of *in vitro* and *in vivo* assays depend on the nature of the product. The safety from contamination by potentially infectious adventitious agents, toxicity, genotoxicity, biomaterials compatibility, immunogenicity and inflammatory responses are typical for tissue engineered products. The ASTM is making a concerted effort to establish standards and guidelines for the entire field of tissue-engineered medical products. Safety, consistency and functionality of biomaterials used as matrices, scaffolds and immobilizing agents in tissue-engineered medical products are of concern. The evaluation of cellular materials fall outside the range of ISO 10993, EU and other international standards. The details of the safety and challenges will be discussed during the presentation.

BIOGRAPHY

PV Mohanan obtained BSc, MSc from Calicut University and PhD from Kerala University. He was a JSPS Post-Doctoral Fellow at the University of Tsukuba, Japan in the field of Neurotoxicity. He joined at Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) in 1989 and has spent 30 years of professional life here. As a toxicologist he has been intimately associated with all the medical devices/technologies developed at SCTIMST. Currently he heads the Division of Toxicology. He is a Visiting Professor and Visiting Researcher at Tokyo University, Japan and a Certified Biological Safety Specialist. He received lifetime achievement award from the Society of Toxicology, India for the outstanding contribution in the field of toxicology. He has been teaching toxicology to Postgraduates and guiding research scholars. Development of Human-on-a-chip is a new mega project, apart from several other funded research projects. He got a Patent for an ELISA kit for the measurement of pyrogenicity. He made significant contributions for the development of medical device regulations in India.

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